



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Atty. Docket No. 98-541-C)

SAD
PATENT 114
6.19.01
RECEIVED
MAY 22 2001

In re Application of:)
Christensen et al.)
Serial No.: 09/721,096)
Filed: November 22, 2000)
For: Removal of Embedding Media from)
Tissue Samples and Cell Tissue)
Conditioning in Automated Immuno-)
histochemical Instrumentation)

Bex
Examiner: Not Assigned 1700
Group Art Unit: 1743
Confirmation No. 4217

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.97 & 1.98, the Applicants wish to make the following references listed on the enclosed Form PTO/SB/08 of record in the above-identified application. This Information Disclosure Statement is in compliance with the continuing duty of candor as set forth in 37 C.F.R. Section 1.56.

Copies of the references cited on the Form PTO/SB/08 are enclosed. Also, attached to each reference in a language other than English is a translation of that reference or an explanation of the relevance of that reference in accordance with 37 C.F.R. § 1.98 (a) (3). For Information Disclosure Statements submitted after receipt of a foreign Search Report, a copy of such Search Report is attached.

The Examiner is respectfully requested to consider the references in their entirety and to so indicate by initialing the appropriate box on the Form PTO/SB/08. The filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made. Likewise, the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

U.S. Patent Documents

5,244,787	Key <i>et al.</i>	September 14, 1993
5,273,905	Muller <i>et al.</i>	December 28, 1993
4,043,292	Rogers <i>et al.</i>	August 23, 1977
5,023,187	Koebler <i>et al.</i>	June 11, 1991
5,614,376	Copley <i>et al.</i>	March 25, 1997
5,595,707	Copeland <i>et al.</i>	January 21, 1997
5,601,141	Gordon <i>et al.</i>	February 11, 1997
4,858,155	Okawa <i>et al.</i>	August 15, 1989
4,865,986	Coy <i>et al.</i>	September 12, 1989
4,543,236	von Gise	September 24, 1985
4,644,807	Mar	February 24, 1987
4,746,491	Ohlin	May 24, 1988
4,888,998	Buzza <i>et al.</i>	December 26, 1989
5,417,123	D'Autry	May 23, 1995
5,645,144	Bogen <i>et al.</i>	July 8, 1997
4,384,193	Kledzik <i>et al.</i>	May 17, 1983
5,075,079	Kerr <i>et al.</i>	December 24, 1991
4,629,862	Kitagawa <i>et al.</i>	December 16, 1986

Foreign Patent Documents

WO 93/09486 Hybaid Ltd. May 13, 1993

Other Documents

1. **Bankfalvi, A. *et al.*** (1994) "Wet autoclaving pretreatment for antigen retrieval in diagnostic immunohistochemistry." *Journal of Pathology* **174**: 223-228.
2. **Fox, C.H. *et al.*** (1985) "Formaldehyde fixation." *Journal of Histochemistry and Cytochemistry* **33** (8): 845-853.
3. **Kawai, K. *et al.*** (1994) "Heat-induced antigen retrieval of proliferating cell nuclear antigen and p53 protein in formalin-fixed, paraffin-embedded sections." *Pathology International* **44**: 759-764.
4. **Mason, J.T. & O'Leary, T.J.** (1991) "Effects of formaldehyde fixation on protein secondary structure: a calorimetric and infrared spectroscopy investigation." *Journal of Histochemistry and Cytochemistry* **39** (2): 225-229.

5. **MaWhinny, W.H.B. et al.** (1990) "Automated immunohistochemistry." *Journal of Clinical Pathology* **43**: 591-596.
6. **McNicol, A.M. & Richmond, J.A.** (1998) "Optimizing immunohistochemistry: antigen retrieval and signal amplification." *Histopathology* **32**: 97-103.
7. **Miller, R.T. & Estran, C.** (1995) "Heat-induced epitope retrieval with a pressure cooker." *Applied Immunohistochemistry* **3** (3): 190-193.
8. **Morgan, J.M. et al.** (1994) "Possible role of tissue-bound calcium ions in citrate-mediated high-temperature antigen retrieval." *Journal of Pathology* **174**: 301-307.
9. **Norton, A.J. et al.** (1994) "Brief, high-temperature heat denaturation (pressure cooking): a simple and effective method of antigen retrieval for routinely processed tissues." *Journal of Pathology* **173**: 371-379.
10. **Pasha, T. et al.** (1995) "Nuclear antigen retrieval utilizing steam heat." *Laboratory Investigations* **72**: 167A, abstract #979.
11. **Pertschuk, L.P. et al.** (1994) "Estrogen receptor immunocytochemistry: the promise and the perils." *Journal of Cellular Biochemistry suppl.* **19**: 134-137.
12. **Pons, C. et al.** (1995) "Antigen retrieval by wet autoclaving for p53 immunostaining." *Applied Immunohistochemistry* **3** (4): 265-267.
13. **Shi, S.-R. et al.** (1997) "Antigen retrieval immunohistochemistry: past, present, and future." *Journal of Histochemistry and Cytochemistry* **45** (3): 327-343.
14. **Sibony, M. et al.** (1995) "Methods in laboratory investigation: Enhancement of mRNA *in situ* hybridization signal by microwave heating." *Laboratory Investigation* **73** (4): 586-591.
15. **Sperry, A. et al.** (1996) "Microwave treatment enhances detection of RNA and DNA by *in situ* hybridization." *Diagnostic Molecular Pathology* **5** (4): 291-296.
16. **Stark, E. et al.** (1988) "An automated device for immunohistochemistry." *Journal of Immunological Methods* **107**: 89-92.
17. **Stross, W.P. et al.** (1989) "Automation of APAAP immunocytochemical technique." *Journal of Clinical Pathology* **42**: 106-112.
18. **Taylor, C.R. et al.** (1995) "A comparative study of antigen retrieval heating methods." *CAP Today* **9**: 16-22.
19. International Search Report for application PCT/US99/20353.
20. International Search Report for application PCT/US99/04379.
21. International Search Report for application PCT/US99/04181.

This Information Disclosure Statement is being filed:

within three months of the filing date of a national application; within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 in an international

application; or before the mailing date of a first Office Action on the merits. 37 C.F.R. §1.97 (b)

after three months of the filing date of a national application, or the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 in an international application; or **after** the mailing date of a first Office Action on the merits, but **before** the mailing date of a Final Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311 (whichever occurs first), and includes (37 C.F.R. § 1.97 (c)):

the Certification under 37 C.F.R. § 1.97(e) (see "Certification" below)

OR

the fee of \$180 set forth in 37 C.F.R. § 1.17(p) (see "Fees" below).

after a Final Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311 (whichever occurs first), but before, or simultaneously with, the payment of the issue fee, and includes the Certification under 37 C.F.R. § 1.97(e) (see "Certification" below), and the Petition Fee set forth in 37 C.F.R. § 1.17(i) (see "Fees" and "Method of Payment of Fees" below). Applicants hereby petitions for consideration of the Information Disclosure Statement submitted herewith and the accompanying references in examination of the subject patent application.

CERTIFICATION

The **undersigned** hereby certifies that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.

The **undersigned** hereby certifies that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

FEES

No fee is owed by the applicant(s).

The **IDS Fee of \$180.00** under 37 C.F.R. § 1.17(p) is enclosed herewith.

The **Petition Fee of \$130.00** set forth in 37 C.F.R. § 1.17(i) is enclosed herewith.

METHOD OF PAYMENT OF FEES

Attached is a check in the amount of \$.

Charge Deposit Account No. 13-2490 in the amount of \$. (A duplicate copy of this communication is enclosed for that purpose.)

FILING OF CORRESPONDENCE BY EXPRESS MAIL UNDER 37 CFR § 1.10

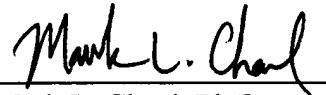
The undersigned states that this Information Disclosure Statement and any documents referred to herein as being attached or enclosed are being deposited as Express Mail to Addressee (Express Mail No.: EL 738004947 US) with the United States Postal Service with sufficient postage in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231 on May 18, 2001.

REMARKS

Consideration of the cited information herein is respectfully requested. Should there be any questions regarding this Information Disclosure Statement, the Examiner is invited to contact the undersigned. Please charge any underpayment or credit any overpayment of fees occasioned by this communication to Deposit Account No. 13-2490.

Respectfully submitted,

Date: May 18, 2001



Mark L. Chael, Ph.D.
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Approved for use through 10/31/2002. OMB 0651-0031

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MAY 18 2000 INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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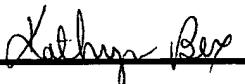
Sheet	3	of	4	Attorney Docket No.	98,541-C
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Complete if Known

Application N.	09/721,096
Filing Date:	November 22, 2000
First Named Inventor	Christensen
Group Art Unit	1743
Examiner Name	unassigned

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
D	T	Bankfalvi, A. et al. (1994) "Wet autoclaving pretreatment for antigen retrieval in diagnostic immunohistochemistry." <i>Journal of Pathology</i> 174: 223-228.	
	U	Fox, C.H. et al. (1985) "Formaldehyde fixation." <i>Journal of Histochemistry and Cytochemistry</i> 33 (8): 845-853.	
	V	Kawai, K. et al. (1994) "Heat-induced antigen retrieval of proliferating cell nuclear antigen and p53 protein in formalin-fixed, paraffin-embedded sections." <i>Pathology International</i> 44: 759-764.	
	W	Mason, J.T. & O'Leary, T.J. (1991) "Effects of formaldehyde fixation on protein secondary structure: a calorimetric and infrared spectroscopy investigation." <i>Journal of Histochemistry and Cytochemistry</i> 39 (2): 225-229.	
	X	MaWhinny, W.H.B. et al. (1990) "Automated immunohistochemistry." <i>Journal of Clinical Pathology</i> 43: 591-596.	
	Y	McNicol, A.M. & Richmond, J.A. (1998) "Optimizing immunohistochemistry: antigen retrieval and signal amplification." <i>Histopathology</i> 32: 97-103.	
	Z	Miller, R.T. & Estran, C. (1995) "Heat-induced epitope retrieval with a pressure cooker." <i>Applied Immunohistochemistry</i> 3 (3): 190-193.	
	AA	Morgan, J.M. et al. (1994) "Possible role of tissue-bound calcium ions in citrate-mediated high-temperature antigen retrieval." <i>Journal of Pathology</i> 174: 301-307.	
	AB	Norton, A.J. et al. (1994) "Brief, high-temperature heat denaturation (pressure cooking): a simple and effective method of antigen retrieval for routinely processed tissues." <i>Journal of Pathology</i> 173: 371-379.	
	AC	Pasha, T. et al. (1995) "Nuclear antigen retrieval utilizing steam heat." <i>Laboratory Investigations</i> 72: 167A, abstract #979.	
	AD	Pertschuk, L.P. et al. (1994) "Estrogen receptor immunocytochemistry: the promise and the perils." <i>Journal of Cellular Biochemistry</i> suppl. 19: 134-137.	
	AE	Pons, C. et al. (1995) "Antigen retrieval by wet autoclaving for p53 immunostaining." <i>Applied Immunohistochemistry</i> 3 (4): 265-267.	
	AF	Shi, S.-R. et al. (1997) "Antigen retrieval immunohistochemistry: past, present, and future." <i>Journal of Histochemistry and Cytochemistry</i> 45 (3): 327-343.	
	AG	Sibony, M. et al. (1995) "Methods in laboratory investigation: Enhancement of mRNA <i>in situ</i> hybridization signal by microwave heating." <i>Laboratory Investigation</i> 73 (4): 586-591.	
D	AH	Sperry, A. et al. (1996) "Microwave treatment enhances detection of RNA and DNA by <i>in situ</i> hybridization." <i>Diagnostic Molecular Pathology</i> 5 (4): 291-296.	

Examiner Signature		Date Considered	10/11/02
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English translation is attached.

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C. Complete if Known

Application N

09/721.096

Filing Date:

November 22, 2000

First Name

Christens

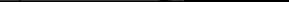
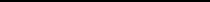
Group Art Unit

MA743

Examiner Name

unassigned 2001

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

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Application No.	09/721,096
Filing Date:	November 22, 2000
First Named Inventor	Christensen
Group Art Unit	1743 22 2001
Examiner Name	unassigned

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Sheet 1 of 4 Attorney Docket No. 98,541-C700

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Figures Appear
		Number	Kind Code ² (if known)			
G	A	5,244,787		Key et al.	09-14-1993	
	B	5,273,905		Muller et al.	12-28-1993	
	C	4,043,292		Rogers et al.	08-23-1977	
	D	5,023,187		Koebler et al.	06-11-1991	
	E	5,614,376		Copley et al.	03-25-1997	
	F	5,595,707		Copeland et al.	01-21-1997	
	G	5,601,141		Gordon et al.	02-11-1997	
	H	4,858,155		Okawa et al.	08-15-1989	
G	I	4,865,986		Coy et al.	09-12-1989	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
G	J	WO	93/09486		Hybaid Ltd.	05-13-1993		

Examiner Signature	<i>Dalby Bex</i>	Date Considered	10/11/02
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Sheet 2 of 4 Attorney Docket No. 98-541-0

1700

U.S. PATENT DOCUMENTS

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		Number	Kind Code ² (if known)			
OS	K	4,543,236		von Gise	09-24-1985	
	L	4,644,807		Mar	02-24-1987	
	M	4,746,491		Ohlin	05-24-1988	
	N	4,888,998		Buzza et al.	12-26-1989	
	O	5,417,123		D'Autry	05-23-1995	
	P	5,645,144		Bogen et al.	07-8-1997	
Q	Q	4,384,193		Kledzik et al.	05-17-1983	
✓	R	5,075,079		Kerr et al.	12-24-1991	
OS	S	4,629,862		Kitagawa et al.	12-16-1986	

FOREIGN PATENT DOCUMENTS

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		Office ³	Number ⁴	Kind Code ⁵ (if known)				

Examiner Signature	<i>John R. B.</i>	Date Considered	10/11/02
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